Statistical Analysis Plan (SAP) for Study UB-313-101

A First-in-Human Study to Evaluate the Safety, Tolerability, and Immunogenicity of UBITh® Migraine Immunotherapeutic Vaccine (UB-313) in Healthy Participants

Date: 7 November 2023

Version 2.0

Signature Page

I have reviewed this Statistical Analysis Plan and approve its contents.

[redacted]
Author
Study Statistician
[redacted]

Signature: [redacted]

Date: 11/9/2023

[redacted]
Project Statistician
[redacted]

Signature: [redacted]

Date: 11/9/2023

[redacted]
Senior Director, Clinical Development
Global Product Lead
Vaxxinity, Inc.

Signature: [redacted]

Date: 11/9/2023

[redacted]
Director, Clinical Operations
Vaxxinity, Inc.

Signature: [redacted]

Date: 11/9/2023

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1.0 Introduction

This Statistical Analysis Plan (SAP) provides describes the statistical analyses outlined and specified in the Protocol UB-313-101 Version 2.0: A First-in-Human Study to Evaluate the Safety, Tolerability, and Immunogenicity of UBITh® Migraine Immunotherapeutic Vaccine (UB-313) in Healthy Participants, dated 14 June 2022.

2.0 Study Objectives and Design

2.1 Objectives and Endpoints

The primary, secondary, and exploratory objectives and endpoints of this study are shown below.

Table 1. Objectives and Endpoints

Objectives	Endpoints
Primary Safety and Tolerability	
To evaluate the safety and tolerability of UB-313, when administered at selected dose regimens given intramuscularly (IM) to healthy adults.	Safety will be assessed by adverse events (AEs), adverse events of special interest (AESIs), medically attended adverse events (MAAEs), local (injection site) and systemic (generalized) reactions (i.e., reactogenicity), clinical laboratory assessments (e.g., chemistry, hematology, urinalysis), vital signs, neurological and physical examinations and electrocardiograms (ECGs), through the end of study.
Primary Immunogenicity	
To evaluate the anti-Calcitonin Gene-Related Peptide (anti-CGRP) specific antibody responses to selected UB-313 dose regimens in healthy adults.	Immunogenicity will be measured serum anti-CGRP antibody titers and analyzed from baseline to Week 16 and Week 44.
Secondary	
To evaluate the effects of selected UB-313 dose regimens on capsaicin-induced dermal blood flow (DBF) as a surrogate marker of target engagement.	Pharmacodynamics (PD) of the immune response will measured by the inhibition of capsaicin-induced increase in DBF and will be analyzed from baseline to Week 16 and until return to baseline or until Week 44, whichever comes first.
Exploratory	
To evaluate the effects of selected UB-313 dose regimens on CGRP concentrations in serum.	CGRP concentrations in serum through the end of study.
To characterize antibodies generated by UB-313.	Antibody titers against components of the UB-313 (i.e., CpG1 and UBITh1) through the end of study. Isotype-specific anti-CGRP antibody titers through the end of study.

To examine cytokine release induced by UB-313.	Cytokine release from peripheral blood mononuclear cell (PBMC)s stimulated with component of the UB-313 (T-cell ELISpot) through Week 16.

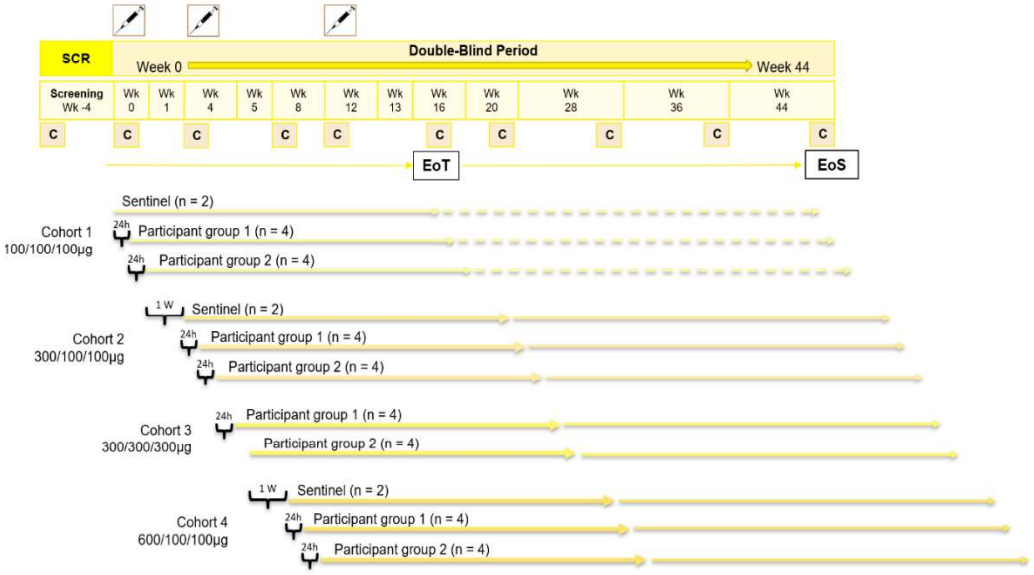
2.2 Study Design

This is a single-site, randomized, double-blind, placebo-controlled, multi-dose regimen, first-in-human study of UB313, an anti-CGRP peptide-based immunotherapy candidate. Details for study design are described in protocol section 3.

The study design is shown in

Figure **1**.

Figure 1 Study Design Schematic



*No more than 4 participants will be dosed in a 24-hour period.

*No more than 4 participants will be dosed in a 24-hour period.

Abbreviations: C (capsaicin Challenge); EoS (End of Study); EoT (End of Treatment); M (month); SCR (Screening Period); h (hour); Wk (week).

SRC (Safety Review Committee) is responsible for the safety review and dose escalation decision. At the end of Week 16, an EoT analysis will be performed for each cohort, unblinded by treatment cohort and pooled by dose on all safety, tolerability, immunogenicity and DBF data. At the end of the treatment analysis, study team members who are responsible for the conduct and data management of the study, and participants will remind blinded to the subject level treatment assignment. If there are no safety concerns, the study will continue until all participants complete Week 44 (End of Study [EoS]) visit. An unblinded statistics team from an external CRO (AvanSight) will perform the EOT and EOS analyses.

3.0 Analysis Sets

The following populations sets will be used for the analyses.

- Full Analysis Set (FAS) consists of all participants randomized and received all three administrations of study Investigational Medicinal Product (IMP) per protocol, and who have at least one evaluable post baseline assessment of the anti-CGRP antibody titers.
- Safety Analysis Set (SS) consists of all participants who receive at least 1 dose of study IMP.

Demographic, baseline, and safety analysis will be based on Safety Analysis Set. Immunogenicity analyses, pharmacodynamics (PD) analyses, and exploratory analyses will be performed for FAS.

4.0 General Consideration

All analyses will be conducted using observed data only and no missing data will be imputed.

In general, the baseline value is defined as the last available value before the first injection of study dose.

All analysis and summary will be performed by dose group, defined as below:

- 100/100/100µg (8 active participants in cohort 1)
- 300/100/100µg (8 active participants in cohort 2)

- 300/300/300µg (8 active participants in cohort 3)
- 600/100/100µg (8 active participants in cohort 4)
- Placebo (8 participants from all cohorts)

5.0 Statistical Analyses

5.1 Immunogenicity, Pharmacodynamics, and Exploratory Analyses

Efficacy analysis will be based on FAS. All analyses and plot will be performed by dose group for each visit and each timepoint unless otherwise specified. In general, summary of a variable (e.g., titer, CIDBF) will include baseline, actual value, and change (or percent change) from baseline when applicable. Summary plots will be done when applicable.

For qualtititive assessements (e.g., titer value, CIDBF…), the distribution will be examined. If the distribution is similar to log normal, log transformation will be applied. In this case, geometric mean and GMR (Geometric Mean Ratio) will be presented in place of mean and difference. For model analysis, log transformed value will be used, analysis results will be presented after anti log transformation.

5.1.1 Immunogenicity Analyses

5.1.1.1 Serum anti-CGRP Antibody Titers (Primary Endpoint and Analysis)

The primary immunogenicity endpoint is serum anti-CGRP antibody titers.

The anti-CGRP antibody titers and change from baseline will be summarized at each visit.

Comparison between each UB-313 groups and Placebo group in change from baseline will be based on an analysis of covariance (ANCOVA) model including dependent variable of change from baseline in titer values at each postbaseline visit, with factor of treatment, and baseline titer as covariate.

5.1.1.2 Serum anti-CGRP Antibody Titers vs Age and Gender (Exploratory)

Relationship between immunogenicity and age, and gender differences in immunogenicity will be explored.

Serum anti-CGRP antibody titers will be summarized by gender.

5.1.1.3 Seroconversion and Responder Rate (Exploratory)

Additional exploratory endpoints are seroconversion status and sero responder status for each participant.

Seroconversion is defined as the ratio (i.e., geometric mean fold change) of post baseline titer over baseline titer ≥ X (e.g., X=1, 2, 3, 4).

Seroconversion rates will be calculated for all postbaseline visits along with 95% CIs based on Binomial distribution. In addition, the difference in the response rates between UB-313 and the placebo group (UB-313 – placebo) will be calculated, and the 95% CIs based on Fisher's Exact test will be displayed.

To define the threshold of response, mean and standard deviation of titer values will be calculated using the assessments below.

- Titer values at baseline from all participants

and

- Titer values at all postbaseline visits up to Week 16 from placebo participants.

The mean plus two standard deviations (mean+2SD) will be used as the threshold of response. Responders will be defined as the participants with titer value greater than or equal to response threshold for each visit including baseline and postbaseline visits.

Responder analysis will be done similarly to seroconversion rates.

5.1.1.4 Cumulative AUC for Serum anti-CGRP Antibody Titer and C_{max} (Exploratory)

Cumulative AUC is defined as the area under the curve from Day 1 to each scheduled visit. AUC will be calculated by the sum of individual trapezoid area under the curve of level of antibodies.

AUC from baseline to each postbaseline visit will be calculated. AUC above baseline for each postbaseline will also be calculated (i.e., derive AUC using each postbaseline value change from baseline). In the case of early dropout, the AUC will be calculated up to the last visit with titer values. AUC will not be calculated for the visits after dropout.

C_{max} is the highest observed value up to end of study (EoS). C_{max} change from baseline will be calculated as C_{max} – baseline value.

ANCOVA model will include dependent variable of cumulative AUC and AUC above baseline, with factor of dose group, and baseline titer as covariate. C_{max} and C_{max} change from baseline will be analyzed similarly.

5.1.1.5 Quantitative anti-CGRP Antibody Titers (Exploratory)

Quantitive anti-CGRP antibody titers will be summrized.

5.1.2 Pharmacodynamics (PD) Analyses

5.1.2.1 Capsaicin Induced Dermal Blood Flow (Secondary Endpoint and Analysis)

Capsaicin-induced increase in DBF (CIDBF)

The pharmacodynamics (PD) endpoint is the inhibition of capsaicin-induced increase in DBF (CIDBF). The DBF at each timepoint at each visit will be calculated as the average of two capsaicin-induced locations.

The DBF will be summarized for each timepoint (i.e., 0, 15, 30, 45, and 60 minutes) at each visit (i.e., Day 1, Day 29, Day 57, Day 85, Day 113, and Day 141, Day 197, Day 253, Day 309 as applicable).

Change and Percent Change from pre capsaicin in CIDBF

For each post capsaicin time point at each visit, change and percent change from pre capsaicin will be calculated. For example, change at 30 minutes post capsaicin on Day 29 from pre capsaicin is calculated as the DBF at 30 minutes post capsaicin on Day 29 minus the DBF at 0-minute pre capsaicin on Day 29. Percent change will be calculated similarly.

Summary will be presented. Between dose group comparison will be done. ANCOVA model will include dependent variable of change (or percent change) from pre capsaicin in CIDBF, with factor of dose group, and DBF at 0-minute pre capsaicin as covariate.

Change and Percent Change from Baseline (Day 1 prior to study IMP) in CIDBF

For 30 minutes and 45 minutes post capsaicin at each visit, change and percent change from baseline (Day 1 prior to study IMP) will be calculated. For example, change from baseline at 30 minutes post capsaicin on Day 29 is calculated as the DBF at 30 minutes post capsaicin on Day 29 minus the DBF at 30 minutes post capsaicin on Day 1 prior to study IMP. Percent change will be calculated similarly.

Summary will be presented. Between dose group comparison will be done. ANCOVA model will include dependent variable of change (or percent change) from baseline in CIDBF, with factor of dose group, and DBF at baseline (Day 1 prior to study IMP) as covariate.

DBF for Non-capsaicin Vehicle Control

DBF from control location (vehicle RD) will be summarized for each dose group and each visit as well as for pooled group and all visits.

5.1.2.2 CIDBF by Gender (Exploratory)

DBF and change from pre capsaicin will be summarized by gender for baseline, week 16 and week 44.

5.1.2.3 CIDBF AUC (Exploratory)

CIDBF AUC (0-60min) and change from baseline (Day 1 prior to study IMP) will be summarized by dose group for each visit. Between dose group comparison will be done. ANCOVA model will include dependent variable of AUC, with factor of dose group, and baseline AUC as covariate.

5.1.2.4 Inhibition Responder (Exploratory)

CIDBF at 30 minutes post capsaicin will be used for the responder analysis. To define threshold of response, mean and standard deviation will be calculated using the assessments below.

- CIDBF at baseline from all participants

The mean minus two standard deviations (mean-2SD) will be used as the threshold of response. CIDBF responders will be defined as the participants with CIDBF less than or equal to response threshold for each visit including baseline and postbaseline visits.

Responder analysis will be done similarly to seroconversion rates.

5.1.2.5 Duration of Inhibition Response (Exploratory)

Duration of inhibition response is defined as from baseline to either return to baseline or until Week 44, whichever comes first for inhibition responders. Participants who do not return to baseline will be censored at the time of study exit.

Duration of inhibition response will be summarized for each dose group, using Kaplan-Meier product-limit estimates.

5.1.3 Other Exploratory Analyses

5.1.3.1 CGRP Concentrations in Serum

Summary will be done.

5.1.3.2 Correlation between CIDBF, anti-CGRP Antibody, aCGRP Concentrations

Correlation between CIDBF AUC (0 to 60 minutes) and anti-CGRP antibody at each visit will be summarized separately by dose group. Pearson's corelation coefficient will be calcaluated.

In addtion, correlation between CIDBF AUC (0 to 60 minutes) and aCGRP concentrations, aCGRP concentrations and anti-CGRP antibody at each visit will be done similarly.

5.1.3.3 Antibodies Against Components of UB-313

Antibody titers against components of UB-313 (include but are not limited to anti-CGRP target epitope, anti-UBITh, and anti-CpG1) will be summarized.

5.1.3.4 Cytokine Release included by UB-313

5.2 Cytokine release from peripheral blood mononuclear cell (PBMC)s stimulated with component of UB-313 (T-cell ELISpot) will be summarized.Safety Analyses

Safety will be assessed by Adverse Events (AEs), Adverse Event of Special Interests (AESIs), medically attended adverse events (MAAEs), local (injection site) and systemic (generalized) reactions (i.e., reactogenicity), clinical laboratory assessments, vital signs, physical neurological and examinations and electrocardiograms (ECGs), through the end of study. Safety analysis will be based on safety analysis set.

5.2.1 Extent of Exposure

The number of injections and total dosage of study drug will be summarized.

5.2.2 Treatment Tolerability

Overall treatment tolerability will be summarized in the safety population.

The overall treatment tolerability of UB-313 for each dose group is defined as the percentage of number of administered doses divided by number of administered doses plus number of missed doses of participant(s) who drops out due to drug-related AE(s). It is calculated according to the following formula:

100% x (A+B1+C+D) / (A+B1+B2+C+D)

where

A: number of administered doses of completers

B1: number of administered doses of participant(s) who drops out due to drug-related AE(s)

B2: number of missed doses of participant(s) who drops out due to drug-related AE(s)

C: number of administered doses of participant(s) who drops out due to drug-unrelated AE(s)

D: number of administered doses of participant(s) who drops out not due to AE(s)

5.2.3 Adverse Events

Adverse events (AEs) will be coded using MedDRA. The actual version of MedDRA will be noted in the statistical tables and clinical study report. The intensity of the AEs is graded according to the Common Terminology Criteria for Adverse Events (CTCAE), version 5.0.

An AE will be considered a treatment-emergent adverse event (TEAE) if the AE began or worsened (increased in severity or became serious) after the first administration of study drug.

A treatment-emergent serious adverse event (TESAE) is defined as an SAE that is also a TEAE.

TEAEs will be summarized by participant incidence rates. The number and percentage of participants with TEAEs will be tabulated for overall (i.e., any preferred term), as well as by primary MedDRA SOC and PT.

5.2.3.1 Adverse Event Overview

An overview of AEs will be presented. The number and percentage of participants experiencing at least one event will be summarized for each of the below categories.

- Treatment related TEAE
- Serious TEAE
- Treatment related serious TEAE
- Adverse events of special interest (AESI)
  AESI is defined in Protocol Appendix 4 ADVERSE EVENTS OF INTEREST. AESI MedDRA terms based on Protocol Table 5 AESIs based on identified adverse reactions and Table 6 AESIs based on important potential risks are listed in Appendix 2.
- Medically attended adverse event (MAAE)
- Death

5.2.3.2 Treatment-Emergent Adverse Events

The number and percentage of participants will be tabulated for the below categories of TEAEs.

- TEAEs by SOC and PT
- TEAEs by SOC, PT and maximum severity

- TEAEs by SOC, PT and maximum relationship
- Treatment-related TEAEs by SOC and PT
- SAEs (including deaths) by SOC and PT
- TEAEs leading to treatment discontinuation by SOC and PT
- AESIs by SOC and PT
- MAAEs by SOC and PT

5.2.3.3 Solicited Adverse Events

Solicited local and systemic AEs are defined in protocol section 7.5.3.2 Reactogenicity Assessment, and protocol appendix 3: Toxicity grading scale for solicited adverse events.

Local (injection site) and systemic (generalized) reactions (i.e., reactogenicity) after each study product injection will be presented by maximum severity. Summary will include counts and percentages of participants by dose group for each reaction and each injection.

5.2.4 Laboratory Data

5.2.4.1 Hematology and Chemistry Parameters

Clinical laboratory values will be reported in International System of Units (SI) units and categorized based on normal ranges collected from laboratories.

Summary and plot will be presented.

The number and percentage of participants who experienced laboratory test abnormalities will be summarized for each lab assay.

For each scheduled postbaseline visit, shift from baseline will be presented based on the categories below:

- Low, Clinically Significant
- Low, Not Clinically Significant
- Normal
- High, Not Clinically Significant
- High, Clinically Significant

Unscheduled visits will be presented in listings but will not be included in summaries.

5.2.4.2 Other Laboratory Parameters

Quantitative data for all other laboratory parameters will be presented using descriptive statistics of values and absolute changes from baseline to each visit. Shift tables will be presented when applicable.

Other laboratory parameters include urinalysis, inflammatory markers, cytokine panel (The cytokine panel will include but is not limited to IFN-γ, IL-2, IL-4, IL-6, IL-8, and TNF-α).

5.2.4.3 Vital Signs

Descriptive statistics for semi-recumbent vital signs including heart rate (HR), systolic and diastolic blood pressure (BP), respiratory rate (RR), body temperature at each visit will be presented.

5.2.4.4 Neurological Examinations

Results will be summarized or listed.

5.2.4.5 Physical Examinations

Results will be summarized or listed.

5.2.4.6 Electrocardiograms (ECGs)

Descriptive statistics for triplicate ECG parameters and changes from baseline values at each visit will be presented. Shift from baseline to the worst postbaseline will be presented.

5.2.5 Other Safety Parameters

5.2.5.1 Height and Weight

Descriptive summary will be done.

5.2.5.2 Pregnancy Test

Positive results will be listed.

5.3 Other Analyses

5.3.1 Study Participants

5.3.1.1 Disposition of Participants

The total number of participants will be summarized below.

- Participants who were screened (who signed informed consent)

Number and percentage of participants in each of the following categories will be summarized.

- Participants who were randomized (this is denominator for the percentages described below
- Participants who received at least one dose of study drug
- Participants who completed treatment period (Week 16)
- Participants who discontinued during the treatment period
    - Reasons for treatment discontinuation (based on reasons reported on CRF)
- Participants who completed the study
- Participants who discontinued from the study
    - Reasons for study discontinuation (based on reasons reported on CRF)

Number of participants in each analysis population will be summarized. Participants excluded from analysis will be listed.

In addition, reasons for screen failure will be summarized.

5.3.1.2 Protocol Deviations

Major protocol deviations will be summarized.

5.3.1.3 Demographics and other Baseline Characteristics

5.3.1.3.1 Demographics

Demographic parameters (age, gender, race, and ethnicity) will be summarized.

5.3.1.3.2 Baseline characteristics

Baseline parameters (height, body weight, BMI) will be summarized.

5.3.1.4 Medical History

Medical history and surgical history that are not ongoing at the trial initiation, and medical history that are ongoing at the trial initiation will be summarized separately. The number and percentage of participants will be tabulated by MedDRA SOC and PT. The actual version of MedDRA will be noted in the statistical tables and clinical study report.

5.3.1.5 Prior and Concomitant Medications

A prior medication is defined as any medication taken prior to the start of study treatment. A concomitant medication is defined as any medication taken after the start of study treatment (i.e., any medication that started prior to the study treatment and continued to be taken after the study treatment or any medication that started after the study treatment).

Prior and concomitant medications will be coded using the World Health Organization (WHO) Drug Dictionary. The actual version of WHO will be noted in the statistical tables and clinical study report. The number and percentage of participants reporting prior or concomitant medications will be summarized separately by Anatomical Therapeutic Chemical (ATC) 1st level class and preferred drug name. If more than one medication is coded to the same preferred drug name for the same participant, the participant will be counted only once for that preferred drug name.

6.0 Additional details not mentioned in the protocol

Additional details and specifications have been included in this SAP to allow for better understanding of the intended methods. Additional analyses (including exploratory and subgroup assessments) for select variables have been added. Additional sensitivity analyses will be conducted to explore any effects related to the presence of data outliers.

7.0 Version History

SAP Version	Approval Date	Change	Rationale
1	17 May 2023	Not Applicable	Original version

2		Added AUC above baseline for anti-CGRP antibody titers in section 5.1.1.4.	To adjust for baseline.
		Added C_{max} for anti-CGRP antibody titers in section 5.1.1.4.	To capture maximum titer level.
		Added text for CI DBF AUC in section 5.1.2.3.	Updated for clarity.
		Moved cytokine release from section 5.2.4.2 to section 5.1.3.4.	Updated for clarity.

Appendix 1 List of Abbreviations

Abbreviation	Definition
ADA	Anti-drug antibody
AE	Adverse event
AESI	Adverse event of special interest
ANCOVA	Analysis of Covariance
BP	Blood pressure
CI	Confidence interval
COVID-19	Coronavirus disease 2019
CRF	Case report form (electronic or paper)
CRO	Contract research organization
DBP	Diastolic blood pressure
ECG	Electrocardiogram
EOS	End of study
EOT	End of treatment
FIH	First-in-human
GMR	Geometric Mean Ratio
HR	Heart rate
IMP	Investigational Medicinal Product
MedDRA	Medical Dictionary for Regulatory Activities
NA	Not applicable
NCS	Not clinically significant
PE	Physical examination
PD	Pharmacodynamic
PP	Pulse pressure
PT	Preferred term
SAE	Serious adverse event

Abbreviation	Definition
SS	Safety analysis set
SAP	Statistical analysis plan
SD	Standard deviation
SOC	System organ class
TEAE	Treatment-emergent adverse event
VS	Vital signs

Appendix 2 MedDRA Terms for AESI

Preferred Term Code	Preferred Term	Primary System Organ Class Code	Primary System Organ Class
10047340	Vertigo	10013993	Ear and labyrinth disorders
10010774	Constipation	10017947	Gastrointestinal disorders
10028034	Mouth ulceration	10017947	Gastrointestinal disorders
10030985	Oral mucosa bleeding	10017947	Gastrointestinal disorders
10042128	Stomatitis	10017947	Gastrointestinal disorders
10016256	Fatigue	10018065	General disorders and administration site conditions
10022052	Injection site bruising	10018065	General disorders and administration site conditions
10022061	Injection site erythema	10018065	General disorders and administration site conditions
10022075	Injection site induration	10018065	General disorders and administration site conditions
10022086	Injection site pain	10018065	General disorders and administration site conditions
10022093	Injection site pruritus	10018065	General disorders and administration site conditions
10022094	Injection site rash	10018065	General disorders and administration site conditions
10022095	Injection site reaction	10018065	General disorders and administration site conditions
10053425	Injection site swelling	10018065	General disorders and administration site conditions
10030095	Oedema	10018065	General disorders and administration site conditions
10042674	Swelling	10018065	General disorders and administration site conditions
10002198	Anaphylactic reaction	10021428	Immune system disorders
10002218	Anaphylaxis	10021428	Immune system disorders
10020751	Hypersensitivity	10021428	Immune system disorders
10028810	Nasopharyngitis	10021881	Infections and infestations
10028334	Muscle spasms	10028395	Musculoskeletal and connective tissue disorders
10001760	Alopecia	10040785	Skin and subcutaneous tissue disorders
10002424	Angioedema	10040785	Skin and subcutaneous tissue disorders
10005191	Blister	10040785	Skin and subcutaneous tissue disorders
10064579	Exfoliative rash	10040785	Skin and subcutaneous tissue disorders
10037087	Pruritus	10040785	Skin and subcutaneous tissue disorders
10037844	Rash	10040785	Skin and subcutaneous tissue disorders
10037855	Rash erythematous	10040785	Skin and subcutaneous tissue disorders
10037876	Rash papular	10040785	Skin and subcutaneous tissue disorders
10037884	Rash pruritic	10040785	Skin and subcutaneous tissue disorders
10046735	Urticaria	10040785	Skin and subcutaneous tissue disorders

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Signatures: 4
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Editor Delivery Events	**Status**	**Timestamp**
Agent Delivery Events	**Status**	**Timestamp**
Intermediary Delivery Events	**Status**	**Timestamp**
Certified Delivery Events	**Status**	**Timestamp**
Carbon Copy Events	**Status**	**Timestamp**
Witness Events	**Signature**	**Timestamp**
Notary Events	**Signature**	**Timestamp**
Envelope Summary Events	**Status**	**Timestamps**
Envelope Sent	Hashed/Encrypted	11/9/2023 11:43:51 AM
Certified Delivered	Security Checked	11/9/2023 12:07:48 PM
Signing Complete	Security Checked	11/9/2023 12:08:22 PM
Completed	Security Checked	11/9/2023 12:16:02 PM
Payment Events	**Status**	**Timestamps**
Electronic Record and Signature Disclosure		

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